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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,240	02/08/2001	Valery Kanevsky	10004226-1	6661

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AGILENT TECHNOLOGIES
Legal Department, 51U-PD
Intellectual Property Administration
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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/779,240

Applicant(s)

KANEVSKY ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7, 9-14 and 35-70 is/are pending in the application.
- 4a) Of the above claim(s) 53-70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 9-14 and 35-52 is/are rejected.
- 7) ☒ Claim(s) 42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

Newly submitted claims 53-70 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the methods of claims 53-70 recite different method steps and are apparently directed to different results than is the originally elected method of original claims 1-14. As the new claims recite limitations not recited in the elected claims, they would require a different search.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 53-70 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

An action on the merits of elected claims 1-3, 7, 9-14, and 35-52 follows. All objections and rejections not reiterated below are hereby withdrawn.

Claim Objections

Claim 42 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 42 depends from claim 31, which has been cancelled.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 7, 9-14, 35-52 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Applicant's arguments filed 1/14/04 have been fully considered but they are not persuasive.

As previously set forth in the office action of 10/2/03, the method steps recited do not appear to comprise physical manipulation of matter, but appear to be steps equivalent to mental processes. Although the specification indicates, as argued by applicant on page 15 of the response, that the inventive method MAY be performed by a computer, claims 1-3, 7, 9-13, 35-50 and 52 are not so limited. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant is again reminded that mental processes are not statutory subject matter under 35 USC 101.

It is noted that claims 14 and 51 specifically limit at least some steps to be performed by a processor-based device and are therefore directed to computer-implemented invention. With regard to computer-implemented inventions, applicant argues that transformation of data represents a "safe harbor", and that the claimed method "transforms" features associated with a target into computer data. In response, it is noted that no step of entering data into a computer is recited in the instant claims, nor do the claims recite any step of "transforming" physical data into computerized signals, digitized information, etc. Instant claim 1 merely recites "selecting a predictor

set of features”; selection of data is NOT generally regarded in the art as equivalent to transforming data from one form (e.g. physical) to another (e.g. electronic). Subsequent steps of adding, checking and removing data from a dataset are similarly NOT usually regarded as transforming data from one form to another. As the claims do not recite any physical step which occurs outside the computer nor any step of transforming data, the claims do not recite a “safe harbor”, thus applicant’s argument with regard to a “safe harbor” is not persuasive.

In response to arguments regarding a “concrete, tangible and useful result”, the claimed method appears to be that of a computer process which merely manipulates data but fails to produce any particular result. In fact, it is unclear what the intended result of the claimed method is actually intended to be. Instant claim 1 recites a preamble of “determining a predictor set of features associated with a target” and ends with a step of “removing at least one feature from the predictor set.” While the resultant “set” is certainly a predictor set, it is unclear what relationship that predictor set actually has with any target, nor what significance or use, if any, may be derived from the subtractive predictor set which results from the method. As one skilled in the art would not be able to ascertain what to do with the subtracted predictor set of step (d) of the claimed method, the method does not provide a “concrete, tangible and useful” result. In response to applicant’s request that the examiner identify features of the invention which would render the claim statutory, it is noted that the claims do not recite any specific features, target or relationship between a predictor set and target such that the

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examiner can determine what the actual result of the claimed method is intended to be. Thus, the examiner has not been able to identify statutory features of the invention.

Claims 1-3, 7, 9-14, 35-52 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Applicant's arguments filed 1/14/04 have been fully considered but they are not persuasive. In response to the argument that the claimed method can be used to identify a gene of interest in a sample, or determine a asset of features associated with a target involved in pharmaceutical or therapeutic utility, it is noted that the claims do not recite any genes or diseases, nor any association with pharmaceuticals or therapy. Applicant is reminded that the results of a method must be of "immediate benefit to the public" (See, e.g., *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 USPQ 689, 695 (1966)). Applicant is reminded that a "use" requiring further research is not a utility under 35 USC 101. See MPEP 2107. As set forth above, the claimed method results in a predictor set of features; it is unclear what association, if any, the predictor set has with a target, thus requiring further research. New claims 35 and 36 recite "using" a predictor set (to) predict a target or to determine if a target is in a sample. Where the target itself has a known utility, these claims MAY have utility. However, not every sample which may be detected necessarily has a utility. For example, many nucleic acid sequences do not have established utilities, but may still be detected in a variety of assays. A method of establishing similarity between nucleic acids of unknown function does not, in itself, have utility. Further, the specification broadly defines a "target" on

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page 5 as proteins, genes, immunological information, feature selection for classification, complex biological and chemical data and "components which may be defined over a number of experiments". As a target may be undefined BEFORE performance of the claimed method, detection of an undefined target would not have utility. As previously set forth, the claims do not recite any steps of pattern recognition or classification. Complex biological and chemical data MAY have utility where the data is correlated with an established utility; e.g. a therapeutic use, detection of a disease state, destruction of microorganisms in wastewater, etc. No such correlation is disclosed or recited for any specific biological or chemical data. As the claimed method may be preformed with any data set, and the "uses" set forth may be applied to any data set, the utilities argued are not specific, substantial and credible utilities for the claimed method. For these reasons and those previously set forth, the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Claims 9 and 37 limit a variable wherein "k is a number greater than 1". While various specific values for "k" are recited throughout the specification, specifically $k=2$ and $k=3$, a disclosure that "k" must be "greater than 1" is not found anywhere in the original specification. The original claims did not limit "k". As neither the originally filed claims nor specification provide support for the new limitation of claims 9 and 37, the claims are rejected for reciting new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a step of "checking to see if all of said features are repeated" based on the disclosure of the specification; e.g. on page 11, the examiner interpreted this step to be a checking step to see if the same set of k features have appeared k times in a row. Amended claim 2 now recites repeating steps of claim 1 until determined that all of the features of the predictor set have been repeated k times in a row. New claim 39 limits a checking step to comprise "checking to see if all of ...k features of said predictor set have been repeated k times in a row". It is admitted that claim 39 depends from claim 38, which comprises adding a complement to a set of k-1 features, thus claim 39 further limits the subject matter of a parent claim and is properly dependent. However, as claim 1 was interpreted to comprise a checking step to see if

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all of a number (k) of features have appeared k times in a row, the specific recitation of a limitation for “checking” to see that features have been repeated (appeared?) k times in a row” in dependent claims renders it unclear what (different/broader?) limitation was intended for claim 1. Thus, all of claims 1, 2, and 39 are indefinite.

The term “best” in claims 35, 36, 45, 46, and 49 is a relative term which renders the claim indefinite. The term “best” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification defines a “good solution” on page 7 as a set of predictors with “high enough” quality, but does not define the metes and bounds of a “high enough” quality. The specification also defines a “predictor set” on page 6, but does not define a “best predictor set” anywhere.

Claim 35 recites a step of “using” a set of predictor features “for predicting said target”. It is unclear what the set of predictor features are to be used for; i.e. it is unclear if the set of “features for predicting” are to be used for some unrecited purpose, or if the features are to be used TO predict a target. Further, it is unclear what method steps or steps are intended by the term “using”. For these reasons, claim 35 is indefinite.

Claim 36 recites “using”: a set of predictor features to determine if a target is present in a sample. It is unclear what method steps are intended by the term “using”, therefore the claim is indefinite.

Claim 42 recites “the k-1 subset of features” in line 2. There is no antecedent basis for this term in the claims, therefore the claim is indefinite.

Claim 46 recites the term “incrementing” in line 3. This term is not defined by the specification. The term “increment” is defined by Webster’s dictionary as a noun. Specifically with regard to mathematics, the term “increment” means “the quantity, usually small, by which a variable increases or decreases.” Thus, the term “incrementing” MAY be interpreted to mean increasing OR decreasing. As there is no commonly accepted meaning in the art for the term “incrementing”, and the term is not defined by the specification or in the claims, one skilled in the art would not know what limitation is intended by use of the term, and the claim is indefinite. As set forth in MPEP 2111: “During examination, the claims must be interpreted as broadly as their terms reasonably allow. This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification.” See *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) and *MSM Investments Co. v. Carolwood Corp.*, 259 F.3d 1335, 1339-40, 59 USPQ2d 1856, 1859-60 (Fed. Cir. 2001).

Claim 47 recites the term “incremented” See above for a discussion of the “plain meaning of “increment”. As one skilled in the art would not know the meaning intended for the term “incremented”, claim 47 is indefinite.

Claim 52 limits each of a set of features to comprise “corresponding measurement data.” It is unclear what the measurement data is intended to

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"correspond" to, what has been measured, etc., therefore it is unclear what limitation of the features applicant intends, and the claim is indefinite.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
4/5/04

mam